

distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner has asserted that "[t]he term 'supercharged zinc fetuin' is not defined by the claim, nor does the specification provide a standard for  
5 ascertaining the requisite degree and/or specific activity to be deemed sufficiently supercharged..." Applicant respectfully traverses the Examiner's rejection because Applicant, in the specification, has specifically defined the term "supercharged zinc fetuin".

10 It is well established that an inventor can be his own lexicographer so long as the terms at issue are defined. See e.g. Novo Nordisk of North America, Inc. v. Genentech, Inc., 77 F.3d. 1364, 1369 (Fed. Cir. 1996) ("it has been long accepted that a patentee can be his own lexicographer, provided that he  
15 defines the terms."). Here, "supercharged zinc fetuin" has been clearly defined in the specification. Specifically, the specification states that "supercharged zinc fetuin" is prepared by removing all inorganic ions from fetuin, including zinc, calcium, and barium, and then reloading the fetuin with only  
20 zinc. See page 25, ll. 11-17 of Specification. Therefore, zinc is the only inorganic ion bound to fetuin. In addition, the specification further defines "supercharged zinc fetuin" as increasing the selective apoptotic activity by three to four times as compared to fetuin prepared using the modified Spiro

method. See p. 25, ll. 17-21 of Specification. Therefore, both the requisite degree of zinc, as well as the specific activity associated with "supercharged zinc fetuin" has been defined in the specification. Accordingly, as Applicant has specifically  
5 addressed the Examiner's indefiniteness assertions, Applicant respectfully requests that the Examiner's 35 U.S.C. 112 be withdrawn.

II. Response to 35 U.S.C. 102(b) and 103(a) Rejection.

The Examiner has rejected claims 6-9 pursuant to 35 U.S.C.  
10 102(b) as anticipated, or in the alternative, 35 U.S.C. 103(a) as obvious over *Spiro* and *Tsai*. The Examiner has stated that claims 6-9 are drawn to "product by process claims" which define the product by its method of making. The Examiner has cited In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1995), in asserting that  
15 "if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." The Examiner further states that the *Spiro* article and *Tsai* patent reference isolate a fetal bovine fetuin  
20 which comprises zinc and thus appears to be within the scope of the supercharged zinc fetuin. Applicant respectfully traverses the Examiner's position for Applicant's "supercharged zinc fetuin" is neither the same, nor an obvious product derived from the fetuin disclosed in *Spiro* or *Tsai*.

The fetuin disclosed in *Spiro* and *Tsai* is substantially similar to that disclosed by the Applicant in section (1A) of this application. In that section, Bovine fetuin was prepared using the modified Spiro method. This Spiro fetuin is the precursor to "supercharged zinc fetuin" and is not what is claimed in claims 6-9. The method for making "supercharged zinc fetuin" which uses the Spiro fetuin as a starting agent is disclosed in Section (1F) of this application. This method for producing "supercharged zinc fetuin" includes effectively removing all inorganic ions, including zinc, calcium, and barium from the zinc, and then "supercharging" the fetuin with zinc only. The end product is "supercharged zinc fetuin." This "supercharged zinc fetuin" is neither the same, nor an obvious product of the fetuin generated in *Spiro* or *Tsai*, in that the "supercharged zinc fetuin" has been stripped of all inorganic ions and then reloaded with only zinc. The Spiro and Tsai fetuin, on the other hand, still have other inorganic ions, such as calcium and barium attached to it. Since "supercharged zinc fetuin" is neither the same, nor an obvious derivation of the fetuin derived from *Spiro* and *Tsai*, neither *Spiro* nor *Tsai* anticipates or makes obvious claims 6-9. Accordingly, Applicant respectfully requests that Examiner withdraw his 35 U.S.C. 102(b) and 103(a) rejections.

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III. Response to 35 U.S.C. 102(e) rejection.

The Examiner has rejected claims 6-9 pursuant to 35 U.S.C. 102(e) as anticipated, or in the alternative, 35 U.S.C. 103(a) as obvious over Yu. The Examiner's rejection is based on the  
5 incorrect assertion that "supercharged zinc fetuin" is either the same as or an obvious derivation of the product disclosed in Yu. Applicant respectfully disagrees with the Examiner's position for the two products are neither the same, nor obvious in light of one another.

10 Yu discloses a zinc - charged fetuin which, similar to the Spiro and Tsai fetuin, has other inorganic ions attached to it. In fact, the only difference between the fetuin of Yu versus that of *Spiro* or *Tsai* is that Yu takes the *Spiro*/*Tsai* fetuin and further incubates it with zinc. The Yu zinc - charged fetuin  
15 still has other inorganic ions attached to it. As mentioned above, the method for producing "supercharged zinc fetuin" includes effectively removing all inorganic ions, including zinc, calcium, and barium from the zinc, and then "supercharging" the fetuin with zinc only. The end product is  
20 "supercharged zinc fetuin." This "supercharged zinc fetuin" is neither the same, nor an obvious derivation of Yu's zinc-charged fetuin for the "supercharged zinc fetuin" has been stripped of all inorganic ions and then reloaded with only zinc. Accordingly, since the two products are neither the same, nor

obvious, Applicant respectfully requests the Examiner withdraw the 35 U.S.C. 102(e) rejection pursuant to Yu.

IV. Response to 35 U.S.C. 103(a) rejection.

Finally, the Examiner has rejected claims 1-9 under 35  
5 U.S.C. 103(a) as being unpatentable over Yu. As a basis for  
this rejection, the Examiner has stated that "the Yu patent  
publication discloses 'zinc-charged fetuin' which is apoptotic  
to cancer cells made by the addition of zinc acetate following  
the isolation of bovine fetal fetuin purified by the modified  
10 Spiro method; which 'zinc-charged fetuin' appears to be within  
the scope of the 'supercharged zinc fetuin' presently claimed."  
The Examiner further states that Yu teaches that fetuin produced  
by Sigma lacks apoptotic activity due to the use of EDTA and  
that zinc is the critical ion necessary for apoptotic activity.  
15 Accordingly, the Examiner feels that it would be obvious to one  
skilled in the art to remove other ions with EDTA and then  
incubate the fetuin with zinc.

Applicant respectfully traverses the Examiner's rejection  
because Dr. Yu was under an obligation to assign over her rights  
20 associated with zinc-charged fetuin to Ambryx Biotechnology,  
Inc., which is the same entity to which the present inventor has  
an obligation to assign his inventions. In addition, aside from  
this obligation, Applicant's invention as presently claimed

falls outside of the subject matter indicated, taught or suggested by Yu.

Pursuant to 35 U.S.C. 103(c), subject matter that is developed by another person, which qualifies under 102(e) as  
5 prior art shall not preclude patentability where the subject matter and the claimed invention were, at the time the invention was made, subject to an obligation of assignment to the same person. The zinc-charged fetuin which forms the basis of the Examiner's obviousness rejection was discovered by both Dr. Yu  
10 and Dr. Tsai. This discovery eventually culminated in the issuance of the '298 patent which was then assigned over by Dr. Yu and Dr. Tsai to Ambryx Biotechnology, Inc.

U.S. patent number 5,994,298 (hereinafter "the '298 patent") was issued to Applicant (David Tsai) and Dr. Yu on  
15 November 30, 1999. On July 6, 2000, the '298 patent was assigned over to Ambryx Biotechnology, Inc. (hereinafter "Ambryx") See Assignment of Patent Rights, a true and correct copy of which is attached hereto. The '298 patent discloses the following facts: (1) fetuin purchased from Sigma has low  
20 apoptotic activity; (2) that Sigma was prepared by EDTA which removed the zinc ion; (3) and that removal of this zinc ion may cause the irreversible loss of protein activity. See '298 Patent, col. 17, ll. 40-56. These facts form the basis of the Examiner's obviousness rejection.

Pursuant to 35 U.S.C. 103(c), Yu's printed publication, which qualifies as prior art under 102(e), must not preclude patentability due to the her assignment of the rights to the '298 patent over to Ambryx. In other words, the Examiner has  
5 offered an obviousness rejection pursuant to Yu based on the apoptotic affects associated with zinc and the effects demonstrated by the use of EDTA by Sigma to remove ions. This is precisely the same subject matter that was previously disclosed in the '298 patent. And, since Dr. Yu had assigned  
10 over her rights to Ambryx, 35 U.S.C. 103(c) is applicable, and the Yu reference cannot preclude patentability. Accordingly, Applicant respectfully requests the Examiner withdraw the 35 U.S.C. 103(a) rejection.

Aside from 35 U.S.C. 103(c), Applicant traverses the  
15 Examiner's obviousness rejection on the basis that Applicant's invention as presently claimed falls outside of the subject matter indicated, taught or suggested by Yu. According to MPEP § 706.02(j), "[t]o establish a prima facie case of obviousness, ... the prior art reference (or references when combined) must  
20 teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d. 1438 (Fed.Cir. 1991).

Applicant respectfully traverses this rejection because the reference does not teach or suggest all the claim limitations. Specifically, Applicant's invention requires that the "supercharged zinc fetuin" be stripped of all inorganic ions, and then reloaded with only zinc. Therefore, the supercharged zinc fetuin lacks all other inorganic ions found in fetuin such as calcium or barium. Yu on the other hand does not teach or suggest this. In Yu, fetuin modified using the Spiro method is merely further incubated with Zinc. Therefore, the Yu zinc-charged fetuin still has other ions such as calcium and barium. Applicant's supercharged fetuin, on the other hand only has zinc.

It is not obvious from Yu to remove all the other ions and then load fetuin with zinc. In Yu, it is only obvious that the combination of additional zinc along with the other existing ions increases apoptotic activity. That is, from Yu one is not sure whether the apoptotic activity is linked to zinc alone, or zinc in combination with the other ions. Applicant resolves this issue by demonstrating the apoptotic affects of fetuin bound only with zinc.

The cited art does no more than offer an invitation to experiment. See Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1373 (Fed.Cir.1999) ("However, there must be sufficient disclosure, either through illustrative examples or terminology,



to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. (Citation omitted). Here, however, the teachings set forth in the specifications provide no more than a "plan" or "invitation" for those of skill in the art to experiment practicing antisense in eukaryotic cells; they do not provide sufficient guidance or specificity as to how to execute that plan."). See In re Vaeck, 947 F.2d 488, 496 & n. 23, 20 USPQ2d 1438, 1445 & n. 23 (Fed.Cir.1991). See also In re Stephen E. Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1514 (Fed.Cir.1993) (The court advised, "The general description and the single example in Wright's specification, directed to a uniquely tailored in vitro method of producing in chicken C/O cells a vaccine against the PRNAV avian tumor virus containing live RAV-A virus particles, did not lead me in February of 1983 that invite experimentation to determine whether other vaccines having in vivo immunoprotective activity could be constructed for other RNA viruses."). Applicant merely took this invitation to create a novel, non-obvious, form of fetuin. Accordingly, Applicant respectfully requests withdrawal of the Examiner's obviousness rejections pursuant to Yu.

V. Conclusion.


Based on the aforementioned remarks, it is Applicant's position that this application is in a condition for immediate

allowance, and such action is respectfully requested. If the Examiner believes that a telephone or other conference would be of value in expediting the prosecution of the present application, enabling an Examiner's amendment or other  
5 meaningful discussion of the case, Applicant invites the Examiner to contact Applicant's representative at Trojan Law Offices, 310-777-8399.

Respectfully submitted,  
Trojan Law Offices  
By:

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Date: October 21, 2003

  
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Roy A. Kim

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## ASSIGNMENT OF PATENT RIGHTS

WHEREAS, WE, DAVID TSAI, residing at 2500 Townsgate Rd., Unit C, Westlake Village, CA 91361, U.S.A., and JENNY YU, residing at 2500 Townsgate Rd., Unit C, Westlake Village, CA 91361, U.S.A., have invented certain a new and useful PROTEINS FOR CANCER CELL SPECIFIC INDUCTION OF APOPTOSIS AND METHOD FOR ISOLATION THEREOF, for which an application (No. 09/149,878) for a United States Patent was filed on September 8, 1998, and U.S. Patent (No. 5,994,298) was issued on November 30, 1999, and

WHEREAS, AMBRYX BIOTECHNOLOGY, INC., a California corporation, having its principal place of business at 2500 Townsgate Rd., Unit C, Westlake Village, CA 91361, is desirous of acquiring the entire right, title, and interest in and to said invention, said Patent application and patents which may be granted and issued therefor in the United States and throughout the world;

NOW THEREFORE, in consideration of the sum of one dollar (\$1.00) and other good and valuable consideration, the receipt of which is hereby acknowledged, WE, DAVID TSAI and JENNY YU by these presents do hereby sell, assign, and transfer unto said AMBRYX BIOTECHNOLOGY, INC. the entire right, title, and interest, to said patent for the territory of the United States of America, and through out the world, including any and all foreign rights and Convention priorities, in and to said invention, application, and Letters Patent; said invention, application, and Letters Patent to be held and enjoyed by said AMBRYX BIOTECHNOLOGY, INC. for its use and behoof and for its successors and assigns to the full end of

the term for which said Letters Patent may be granted, as fully and entirely as the same would have been held by me as if this assignment and sale had not been made;

I FURTHER AGREE to execute upon presentation any and all domestic and foreign applications describing and claiming said invention without further consideration, and in conjunction therewith to execute any and all further assignments or other documents that may be required for filing under the International Convention or for recording in patent offices throughout the world.

Dated this 6<sup>TH</sup> day of JULY, 2000,  
at WESTLAKE VILLAGE, CALIFORNIA

Men-Huei Tsai AKA David Tsai  
DAVID TSAI

Jenny Yu AKA Jenny Yu  
JENNY YU

State of CALIFORNIA) SS:  
County of VENTURA)

Before me personally appeared said Individuals  
and acknowledged the foregoing instrument to be their free act and  
deed this 6<sup>TH</sup> day of JULY, 2000.

JAMES S. ROE  
NOTARY SIGNATURE

